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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,184	09/17/2003	Shmuel A. Ben-Sasson	24348-501CIP	5564

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BOSTON, MA 02111

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,184	BEN-SASSON ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59, 64-69, 77-83, 90, 97 and 99-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-59, 64-69, 77-83, 90, 97, 99-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

S.O.O.

DETAILED ACTION

Applicants' election of Invention of Group I, **Claims 1-70, 77-83, 90, 93-97** in response to the restriction requirement mailed November 26, 2004 is acknowledged; however after further analysis of the claims the examiner has realized that due to the broad and encompassing nature of the claims drawn to the composition specifically in regards to: (a) a effective amount of an effectors, (b) a counter ion, (c) a protective agent, (d) non-ionic detergent, (e) a protease inhibitor and a reducing agent, there needs to be a further election with regards to each group.

Claims 10-24 cite a variety of possible compounds that may be considered as effector: polysaccharides glycoasminoglycan, proteins such as insulin, antibodies such as anti-TNF antibodies , an antibiotic, an enzyme, a nucleic acid and so on ... These compounds do not share any sort of function or structure that would allow them to be put together in a Markush type grouping; therefore the examiner has determined that they all are patentably distinct and is requiring the applicant to elect a specific compound. Due to the stated difference among the compounds with regards to structure and function, the election of a specific compound is not considered to a species election.

This application contains claims directed to the following patentably distinct species of the claimed invention: **Claims 25-38** are drawn to counter ions that have different structures and functions: an anionic amphipathic such as

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sulfonate and phosphate, a quaternary amine such as a benzalkonium derivative, imidazolium derivative such as 1,2-dimethyl-3-propylimidazolium and a pyridium derivative such as 1-butyl-4-methylpyridinium.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **claim 25** is generic to counter ion and applicants needs to elect from a group consisting of : an anionic amphipathic such as sulfonate and phosphate, a quaternary amine such as a benzalkonium derivative, imidazolium derivative such as 1,2-dimethyl-3-propylimidazolium and a pyridium derivative such as 1-butyl-4-methylpyridinium.

This application contains claims directed to the following patentably distinct species of the claimed invention: **Claims 46-49** are to a hydrophobic carrier: fatty acids, monoglycerides, di-glycerides, triglycerides, ethers and cholesterol esters of fatty acids.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **claim 46** is generic to hydrophobic carriers applicants needs to elect from a group consisting of fatty acids, monoglycerides, di-glycerides, triglycerides, ethers and cholesterol esters of fatty acids .

This application contains claims directed to the following patentably distinct species of the claimed invention: **Claims 50 and 51** are drawn to protective agents.

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Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **claim 50** is generic to protective agents listed in **claim 51** and applicant needs to elect a single protective agent from **claim 51**.

This application contains claims directed to the following patentably distinct species of the claimed invention: Claims **77-83** are drawn to a non-ionic detergent, an ionic detergent, a protease inhibitor and a reducing agent

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **claim 77** is generic to a non-ionic detergent, an ionic detergent, a protease inhibitor and a reducing agent applicants needs to elect form a group consisting of a non-ionic detergent, an ionic detergent, a protease inhibitor and a reducing agent. Should the applicant elect a protease inhibitor the need to elect a single compound from claim **82** .

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by

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37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


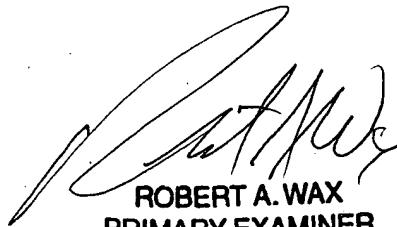
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi


05-12-05
ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653